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| APPLICATION NO                                       | Э.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|--|------|-------------|----------------------|-------------------------|------------------|--|
| 09/814,114   |      | 03/22/2001  | Michael L. Boyer II  | 8932-208-999            | 2083             |  |
| 20582  | 7590 | 10/19/2004  |                      | EXAMINER                |                  |  |
| JONES DAY  |      |             |                      | HAMILTON, LALITA M      |                  |  |
| 51 Louisiana Aveue, N.W<br>WASHINGTON, DC 20001-2113 |      |             | ART UNIT             | PAPER NUMBER            |                  |  |
| W. 101111 VOT 0111, DC 20001 2110                    |      |             |                      | 3624                    | 3624             |  |
|  |      |             |                      | DATE MAILED: 10/19/2004 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)                     |  |  |  |  |  |  |
|---|---|----------------------------------|--|--|--|--|--|--|
|   | 09/814,114  | BOYER ET AL.                     |  |  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit                         |  |  |  |  |  |  |
|   | Lalita M Hamilton   | 3624                             |  |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c  | correspondence address           |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                  |  |  |  |  |  |  |
| Status  |   |                                  |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on RCE  | filed on August 18, 2004.   |                                  |  |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ☑ This  |   |                                  |  |  |  |  |  |  |
|   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                                  |  |  |  |  |  |  |
| Disposition of Claims   |   |                                  |  |  |  |  |  |  |
| 4) ☐ Claim(s) 1-54 and 56-78 is/are pending in the a 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-54 and 56-78 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or  | vn from consideration.  | ,                                |  |  |  |  |  |  |
| Application Papers  |   |                                  |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner   | r.  |                                  |  |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ acce   | )☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |                                  |  |  |  |  |  |  |
| Applicant may not request that any objection to the   | •   |                                  |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correcting 11) The oath or declaration is objected to by the Expression 11.  |   | •                                |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                                  |  |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> <li>3. Copies of the certified copies of the prior application from the International Bureau</li> <li>* See the attached detailed Office action for a list of</li> </ul>  | s have been received. s have been received in Applicati ity documents have been receive (PCT Rule 17.2(a)).   | on No ed in this National Stage  |  |  |  |  |  |  |
|   |   |                                  |  |  |  |  |  |  |
| Attachment(s)   |   |                                  |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | 4) Interview Summary  |                                  |  |  |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date  S. Patent and Trademark Office  | Paper No(s)/Mail Date of Informal P   | ate Patent Application (PTO-152) |  |  |  |  |  |  |

Application/Control Number: 09/814,114

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#### **DETAILED ACTION**

# Request for Continued Examination (RCE)

The request filed on August 18, 2004 for a RCE is acceptable and an RCE has been established. An action follows.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-54 and 56-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce (5,899,939) in view of Boyd (6,206,923).

Boyce discloses the invention substantially as claimed and a body having a substantially tubular inner member and at least one substantially tubular outer member (fig.1-2 and col.6, lines 8-19—further discloses that the device may be formed in any shape); however, Boyce does not disclose each member being formed from a different region in the body or use of cancellous and cortical bone. Boyd teaches a flexible

implant using partially demineralized bone comprising a ring-shaped member (fig.9 and col.6, lines 10-20) and the use of both cancellous and cortical bone (col.7, lines 1-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate each member being formed from a different region in the body and cancellous and cortical bone, as alternative sources of bone that may be used for the device depending on where the implant is needed and ring-shaped members as alternative shapes that may the device may be molded into.

## Response to Arguments

Applicant's arguments with respect to claims 1-55 and 56-78 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin can be reached on (703) 308-1065. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Business Center (EBC) at 866-217-9197 (toll-free).

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